PATENT CL-213

I do hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail on the date indicated below and is addressed to the Commissioner of Patents and Trademarks, Washington, D. C. 20231.

MarilyN Hadil old

late

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Petra Boyle

Gayle D. Wetzel

Kenneth J. Lembach)

Serial No.: 08/026,957

SUPPLEMENTAL AMENDMENT

EXAMINER: R.D. BUDDENS

Filed: March 5, 1993

) ART UNIT: 1806

Title: HUMAN ANTI-TNF

ANTIBODIES

Commissioner of Patents and Trademarks Washington, D.C. 20231

Sir:

Shortly after filing an Amendment on December 22, 1993, the Applicants noted a typographical error on page 4. Please enter the enclosed corrected copy of page 4 so that the revised sentence makes sense.

Respectfully submitted,

Dated: January 7, 1994

James A. Giblin

Attorney for Applicants

Reg. No. 25,772

Miles Inc.

P. O. Box 1986

4th & Parker Streets Berkeley, CA 94701

(510) 420-5511

VII / S 1669

PATENT CL-213

Re 35 USC 101 and 112 (Utility and Enablement):

The Specification and claims 1 - 10 and 12 - 14 were rejected under 35 USC 112 first paragraph on the grounds that the specification does not provide an enabling disclosure in that there is no indication of patentable utility for the claimed antibodies. It is submitted that one Reconsideration is again requested. skilled in the art would readily recognize the value of any monoclonal antibody directed to a specific substance such as TNF. The antibody has been shown to be able to bind to TNF. submitted that a demonstration of a mere binding of human anti-TNF alpha is sufficient demonstration of utility under the patent statute. At the very least, such binding would be useful in simple applications where one would want to use an antibody known to bind selectively with TNF (e.g., an immunoassay or purification step). See, for example, Table 1 on page 13 where the Applicants have TATIFICAN be diluted while still showing binding demonstrated how far to the cited human anti-TNF alpha anti-bedies. Therefore, reconsideration of the basis for rejection is respectfully requested.

Re 35 USC 112, first paragraph (the Cell Line Deposits):

Three of the cell lines used to express the human monoclonal antibodies of the invention have been deposited with ATCC under the Budapest Treaty, as shown on the enclosed deposit notice copies. The undersigned attorney of record hereby certifies that